

§ 331.4

7 CFR Ch. III (1–1–05 Edition)

transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

- (1) Nonviable agents that are, bear, or contain listed agents or toxins;
- (2) Genetic elements or subunits of listed agents or toxins, if the genetic elements or subunits are not capable of causing disease.

§ 331.4 Exemptions.

(a) Diagnostic laboratories¹ and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.² During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) In addition to the exemption provided in paragraph (a) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal or plant health, and animal or plant products. An individual or entity that possesses, uses, or transfers agents or toxins may request

in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.³

§ 331.5 Registration; who must register.

(a) Unless exempted under § 331.4, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register with APHIS.

(b) Each entity must designate an individual to be its responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate an individual to be an alternate responsible

¹However, diagnostic laboratories and other persons will still be required to obtain a permit under part 330 of this chapter in order to import or move interstate any listed agent or toxin.

²A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734-5519. APHIS Form 2040 may be obtained by calling (301) 734-5519 or faxing a request to (301) 734-8700. The form is also available on the Internet at <http://www.aphis.usda.gov/ppq/permits>. The completed form may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.

³A request for exemption may be mailed to biological and Technical Services, PPQ, APHIS, 4700 River road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.

official, who may act for the responsible official when he/she is unavailable. This individual must have the authority and control to ensure compliance with the regulations when acting for the responsible official. This individual will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 331.6 Registration; general provisions.

(a) Unless exempted under this part, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 331.3 without a certificate of registration issued by APHIS.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who controls the entity following a security risk assessment by the Attorney General;⁴ and

(2) Approval of the containment and security of the entity. The entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the containment and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) A certificate of registration will be valid for only the specific agents or toxins listed on the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(d) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in owner-

ship or control of the entity,⁵ changes in the activities involving the agent or toxin). The responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(e) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individual or entities in accordance with § 331.12. The responsible official must notify APHIS 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. We will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(f) A certificate of registration will be valid for a maximum of 3 years.

§ 331.7 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use,

⁴The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

⁵Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.